

REMARKS

This amendment is being filed in response to the Final Office Action dated November 21, 2007. For the following reasons, this application should be considered in condition for allowance and the case passed to issue.

Claims 1-11 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, claim 1, lines 14-15 recited “a processor...configured to automatically supply the medical device with a least one revised treatment guideline.” The Examiner considered the specification as not enabling a processor configured to automatically supply the medical administration device with a treatment guideline, rather the specification teaches that a signal from the processor to the medical administration device indicates that the administration parameters entered into the administration device are appropriate for the medication and the institutional guidelines for the administration have been met [0102]. This recitation does not include a revised treatment guideline. Applicant respectfully disagrees with the Examiner’s conclusion that the specification is not enabling for a processor configured to automatically supply a medical administration device with a treatment guideline. In fact, the application is replete with description regarding the updating or revision of medical treatment guidelines in a medical device provided by a processor.

In paragraph [00014], it states that “Such a system would also be capable of sending a report containing the analysis to personnel within the institution for use in updating the guidelines stored in a medical administration device and/or automatically updating pre-established guidelines or rule sets stored in the device.”

In paragraph [00041], it states “Additionally, the medical treatment data analysis system 4 may determine new guidelines or adjust pre-established guidelines, which may then be communicated to the pharmacy information or hospital administration systems or to patient bedside devices to update a stored database of pre-established guidelines.”

In paragraph [00077], it states “In accordance with the present invention, one or more separate modules may monitor, manage and/or update the institutional guidelines for medical treatments stored in a database at the bedside CPU 80, medication administration device or other location in the institution.”

In paragraph [00080], it states that “In the module 167 is designed to provide a user interface for the medical treatment analysis system 4 at the point-of-care and to receive, or

retrieve, medical treatment guidelines determined by the system for incorporation into a database of such guidelines stored in the point-of-care management system.”

In paragraph [00085], it states “In one embodiment, the determined guidelines may be automatically integrated into a database of medical treatment guidelines. The database may be stored in a medication administration device or an associated bedside CPU.”

In paragraph [000120], it states that “In such case, the PCU would be in contact with institutional information systems, such as the pharmacy information system 20, and receive updated information concerning institutional guidelines for medication administration or other patient area or drug specific information to be used to compare with entered medication and administration information or parameters before beginning administration of a medication to a patient.”

From these many examples, it should be quite apparent that the specification provides more than ample support and for a written description processor that automatically supplies a medical device with at least one revised treatment guideline. Accordingly, the rejection of claims 1-11 under 35 U.S.C. § 112, first paragraph, should be reconsidered and withdrawn.

Claims 1-6, 8-17 and 19-23 were rejected under 35 U.S.C. § 102(b) as being anticipated by Bocionek, et al. (hereafter “Bocionek”). This rejection is hereby traversed and reconsideration and withdrawal thereof are respectfully requested. The following is a comparison of the present invention as currently claimed with the Bocionek reference. Applicant incorporates the arguments made in the amendment filed on September 11, 2007. In addition to these incorporated remarks, the following remarks are made to further clarify and point out the patentability of the claims over the cited reference, as well as to respond to the Examiner’s Response to Arguments in the final office action.

Claim 1 of the present invention requires a processor operatively connected to the memory and which automatically supplies a medical device with at least one revised treatment guideline. It is respectfully submitted that Bocionek fails to show the supplying of medical devices with revised treatment guidelines. The Examiner states that the claim language requires a processor, and since the definition of such entails manipulation of data or the performance of calculations, and the decision functions 15 and 17 generate prompts, medication selection guidance (“revised treatment guideline”) and warnings [0022], it was held by the Examiner that the processor supplies the medical device with treatment guidelines regardless of the fact that the

device controller, used in conjunction with the decision functions that is pointed out by Applicant, to physically or mechanically control the medical administration device.

Applicant fails to see how the medical treatment devices, such as the infusion pumps 85, or ventilators 83, receive the treatment guidelines, as required by the claims. The systems are said to be controlled by the automated device controllers 31. Being controlled is not the same thing as being provided with guidelines. This also goes towards the contention by Applicant that “the optimal drug dosage to be applied by an infusion pump” in Bocionek clearly shows that the device of Bocionek is receiving an instruction and not a guideline. The Examiner, however, submitted that the decision support functions determine optimal drug dosage to be applied by the pump based on medical data, deeming such “instruction” as interpreted by Applicant, as a “treatment guideline”. It is respectfully submitted that the Examiner has more broadly interpreted the term “instruction” to be equivalent to that of “guideline”. As commonly understood, guidelines are generally considered to be limits within which different courses may be followed, as long as those courses fall within those limits. A specific control or instruction, by contrast, does not admit of variation from the specific parameter. In application, the treatment guidelines provided at the medical device allow the medical device to be operated at the point of care somewhere within the parameters provided by the guidelines. A remote controlling of the medical device, in accordance with an instruction sent by the device controllers 31 as in Bocionek, admits of no such flexibility within guidelines. There is nothing in Bocionek that shows supplying of revised treatment guidelines to any of the medical devices. Instead, they are merely controlled by the CCIS application 10. The CCIS databases are central databases, and not distributed. Hence, there is no supplying of medical devices with revised treatment guidelines.

In order to anticipate the claims of an invention under 35 U.S.C. § 102(b), the Examiner must definitively show that a single prior art reference identically discloses each and every element of the claimed invention. It is respectfully submitted that Bocionek fails to satisfy this high burden. The Examiner is attempting to equate the centralized database and control system of Bocionek to the more distributed model of the present invention in which the medical devices are supplied with treatment guidelines, but Bocionek fails to identically disclose such an arrangement. Accordingly, the rejection of claim 1, as well as dependent claims 2-6, 8-10 and 22 should be reconsidered and withdrawn.

Claim 11 of the present application requires means to update treatment guidelines in the medical devices. As with claim 1, Bocionek fails to identically disclose means to update the treatment guidelines in the medical devices, among other features of claim 11 not identically disclosed by Bocionek. For at least the arguments set forth above with respect to claim 1, claim 11 should be considered allowable over Bocionek and the rejection under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

As well, claim 12 and dependent claims 13-17 and 19-21 should be considered allowable for at least the reasons provided above with respect to claims 1 and 11. Reconsideration and withdrawal of the rejection of claim 12 and the dependent claims there from are respectfully requested.

With respect to claim 23, the Examiner has not established that the medication devices have a library of appropriate parameters, with an alarm being activated when a medical treatment guideline having parameters outside of the appropriate parameters is input into the medication device. In fact, the Examiner has not shown that a medical treatment guideline can be input into the medication device, nor has the Examiner shown that the medical devices of Bocionek have a library of appropriate parameters. Again, the Bocionek system is a centralized system, not one in which the medical devices themselves have been shown to have a library of appropriate parameters or medical treatment guidelines. Accordingly, the rejection of claim 23 under 35 U.S.C. § 102(b) should be reconsidered and withdrawn.

In light of the remarks above, this application should be considered in condition for allowance and the case passed to issue. If there are any questions regarding this response or the application in general, a telephone call to the undersigned would be appreciated to expedite the prosecution of the application.

Application No.: 10/726202

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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